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10/19/99

# NEW UTILITY PATENT APPLICATION TRANSMITTAL (Small Entity)

(to be used for new applications only)

Docket No.  
106.101.197

Total Pages in this Submission  
103

**TO THE ASSISTANT COMMISSIONER FOR PATENTS**  
Washington, D.C. 20231

Transmitted herewith for filing under 35 U.S.C. 111(a) and 37 C.F.R. 1.53 is a new utility patent application for an invention entitled:

**MODULATION OF GENE EXPRESSION BY COMBINATION THERAPY**

and invented by:

**Besterman, Jeffrey M.; MacLeod, Alan Robert; and Siders, William M.**

Enclosed are:

## Application Elements

1. ☒ Filing fee as calculated and transmitted as described below
2. ☒ Specification having 94 pages and including the following:
  - ☒ Abstract of the Disclosure
  - ☒ Title of the Invention
  - ☐ Cross References to Related Applications (if applicable)
  - ☐ Statement Regarding Federally-sponsored Research/Development (if applicable)
  - ☐ Reference to Microfiche Appendix (if applicable)
  - ☒ Background of the Invention
  - ☒ Brief Summary of the Invention
  - ☒ Brief Description of the Drawings (if drawings filed)
  - ☒ Detailed Description
  - ☒ Claim(s) as Classified Below
3. ☒ Drawing(s) (when necessary as prescribed by 35 USC 113)
  - ☐ Formal ☒ Informal
  - Number of Sheets 31
4. ☐ Declaration
  - ☐ Executed ☐ Unexecuted ☐ With Power of Attorney ☐ Without Power of Attorney

JC678 U.S. PTO  
09/420692

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## Application Elements (Continued)

5. ☐ Genetic Sequence Submission (if applicable, all must be included)
- ☐ Paper Copy
  - ☐ Computer Readable Copy
  - ☐ Statement Verifying Identical Paper and Computer Readable Copy

## Accompanying Application Parts

6. ☐ Assignment Papers
7. ☐ Computer Program in Microfiche
8. ☐ Information Disclosure Statement/PTO-1449      ☐ Copies of IDS Citations
9. ☐ Petition
10. ☐ Preliminary Amendment
11. ☐ Proprietary Information
12. ☒ Acknowledgment postcard
13. ☒ Small Entity Statement(s) - Specify Number of Statements Submitted: 1 copy
14. ☒ Certificate of Mailing
- ☐ First Class    ☒ Express Mail (Specify Label No.): EL110244036US
15. ☐ Certified Copy of Priority Document(s) (if foreign priority is claimed)
16. ☐ English Translation Document (if applicable)

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## Acc mpanying Application Parts (C ntinued)

### 17. ☒ Additional Enclosures (please identify below):

Copy of Executed Verified Statement (Declaration) Claiming Small Entity Status (37 C.F.R. Section 1.9(f) and Section 1.27(c)) - Small Business Concern from Corresponding Provisional Application U.S. Serial No. 60/104,804, filed October 19, 1998.

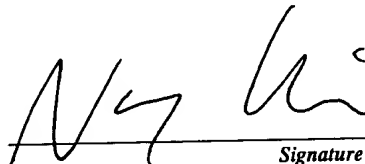
## Fee Calculation and Transmittal

### CLAIMS AS FILED

For	#Filed	#Allowed	#Extra	Rate	Fee
Total Claims	70	- 20 =	50	x \$9.00	\$450.00
Indep. Claims	4	- 3 =	1	x \$39.00	\$39.00
Multiple Dependent Claims (check if applicable) <input checked="" type="checkbox"/>					\$130.00
BASIC FEE					\$380.00
OTHER FEE (specify purpose)					\$0.00
TOTAL FILING FEE					\$999.00

- ☐ A check in the amount of \_\_\_\_\_ to cover the filing fee is enclosed.
- ☒ The Commissioner is hereby authorized to charge and credit Deposit Account No. 08-0219 as described below. A duplicate copy of this sheet is enclosed.
- ☒ Charge the amount of \$999.00 as filing fee.
- ☒ Credit any overpayment.
- ☒ Charge any additional filing fees required under 37 C.F.R. 1.16 and 1.17.
- ☐ Charge the issue fee set in 37 C.F.R. 1.18 at the mailing of the Notice of Allowance, pursuant to 37 C.F.R. 1.311(b).

Dated: October 19, 1999

  
Signature

Nancy Chiu, Ph.D.  
Registration No. 43,545  
Agent for Applicants  
Hale and Dorr LLP  
60 State Street  
Boston, MA 02109  
P: 617-526-6000  
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CC:

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Besterman, Jeffrey M.; MacLeod, Alan Robert; and Siders, William M.  
Serial No.: TO BE ASSIGNED  
Filing Date: HEREWITH  
Docket Number: 106.101.197  
Title: MODULATION OF GENE EXPRESSION BY COMBINATION THERAPY

## BOX PATENT APPLICATION

Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

TRANSMITTAL LETTER

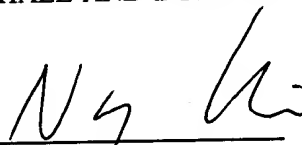
Enclosed herewith for filing in the United States Patent and Trademark office are the following documents:

- 1) New Patent Application Transmittal Cover Sheet (Small Entity) (3 pages);
- 2) Patent Application (97 pages) with 60 pages of specification, 5 pages of claims 1-50, 1 page of abstract, and 31 sheets of informal drawings comprising Figures 1 to 25;
- 3) Copy of Executed Verified Statement (Declaration) Claiming Small Entity Status (37 C.F.R. §1.9(f) and §1.27(c)) - Small Business Concern from Corresponding Provisional Application U.S. Serial No. 60/104,804, filed October 19, 1998 (signed); and
- 4) Return postcard.

This application is a nonprovisional patent application claiming priority to United States Provisional Patent Application Serial No. 60/104,804 filed on October 19, 1998.

Respectfully submitted,

HALE AND DORR LLP



Nancy Chiu, Ph.D.  
Registration No. 43,545  
Agent for Applicants


Hale and Dorr LLP  
60 State Street  
Boston, MA 02109  
Tel. (617) 526-6000  
Fax. (617) 426-5000

Date: October 19, 1999

CERTIFICATE OF MAILING

I hereby certify that the attached papers and fees are being deposited with the United States Postal Service as "Express Mail Post Office to Addressee" Service under 37 C.F.R. 1.10 on October 19, 1999 and is addressed to: BOX PATENT APPLICATION, Assistant Commissioner for Patents, Washington, D.C. 20231.

EL110244036US  
"Express Mail" Label No.



Donna Puleo

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
(Attorney Docket No.106.101.197)

Applicant or  
Patentee: Jeffrey M. Besterman, Robert A. MacLeod, and William M. Siders

Serial No. 60/104,804

Filed or  
Issued: October 19, 1998

For: MODULATION OF DNA METHYLTRANSFERASE  
BY COMBINATION THERAPY

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS  
(37 C.F.R. § 1.9(f) AND § 1.27(c)) - SMALL BUSINESS CONCERN

I hereby declare that I am an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF SMALL BUSINESS CONCERN: MethylGene, Inc.  
ADDRESS OF SMALL BUSINESS CONCERN: 7220 Frederick Banting  
St. Laurent, Quebec, Canada H4S 2A1

I hereby declare that the above-identified small business concern qualifies as a small business concern as defined in 13 C.F.R. § 121.12 and reproduced in 37 C.F.R. § 1.9(d), for purposes of paying reduced fees to the United States Patent and Trademark Office, in that the number of employees of the business concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third part or parties controls or has the power to control both.

I hereby declare that the rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled

MODULATION OF DNA METHYLTRANSFERASE  
BY COMBINATION THERAPY

by the inventors, Jeffrey M. Besterman, Robert A. MacLeod, and William M. Siders, described in

☐ the attached patent application filed herewith

☒ Application Serial No. 60/104,804, filed October 19, 1998

☐ Patent No. \_\_\_\_\_ issued \_\_\_\_\_

If the rights held by the above-identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below\* and no rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 37 C.F.R. § 1.9(c) if that person made the invention, or by any concern which would not qualify as a small business concern under 37 C.F.R. § 1.9(d), or a nonprofit organization under 37 C.F.R. § 1.9(e).

FULL NAME \_\_\_\_\_

ADDRESS \_\_\_\_\_

☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 C.F.R. § 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing therein, or any patent to which this verified statement is directed.

Donald F. Corcoran

NAME OF PERSON SIGNING

President and Chief Executive Officer

TITLE IN ORGANIZATION

7220 Frederick Banting, St. Laurent, Quebec, Canada H4S 2A1

ADDRESS OF PERSON SIGNING

Donald F. Corcoran Donald F. Corcoran

Signature

Date: 1/4/99

\*Note: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 C.F.R. § 1.27).